MAY 1 4 2002

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510(k) Summary of Safety and Effectiveness

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact:	PLUS ORTHOPEDICS 6055 Lusk Blvd. San Diego, CA 92121 Tel: 858-550-3800 x 2506 Attn: Mr. Hartmut Loch, RAC Director, Regulatory Affairs
Trade name:	SL-PLUS® Lateralized Stem
Common name:	Total Hip Joint, Femoral Component, Cementless
Classification name:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented 21 CFR 888.3350 (87 LWJ and 87 JDI)
Equivalence:	SL-PLUS® and SLR-PLUS® Stems, K001942, S/E 7/25/00
Device Modification Description:	We added 12 sizes, sizes 1 through 12, of lateralized stems to the SL-PLUS® Stems, which were cleared for marketing by FDA on 7/25/00 (K001942). These stems allow for a larger offset from 6 mm (size 1) up to 8.5 mm (size 12) compared to the standard SL-PLUS® Stem, thus giving the surgeon a further option to meet the patient's anatomy. The CCD angle is 123° compared to 131° for the standard SL-PLUS® Stem. Material and surface characteristics remain unchanged.
Indications:	The SL-PLUS® Lateralized Stem is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head and neck has been subject to disease or trauma. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.
Contraindications:	Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.
Performance data:	Biomechanical fatigue tests have been performed on the worst-case model. The test results were equal or better to the predicate and other commercially available devices, and they are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2002

Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
Plus Orthopedics
6055 Lusk Blvd.
San Diego, CA 92121-2700

Re: K021178
Trade/Device Name: SL-Plus® Lateralized Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, LWJ
Dated: April 15, 2002
Received: April 15, 2002

Dear Mr. Loch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SPECIAL 510(K) DEVICE MODIFICATION
SL-PLUS® Lateralized Stem
April 15, 2002

510(k) Number: K021178

Device Name(s): SL-PLUS® Lateralized Stem

Indications for Use:

The SL-PLUS® Lateralized Stem is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head and neck has been subject to disease or trauma. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021178

Prescription Use Yes OR Over-The-Counter-Use No
(Per 21 CFR 801.109) (Optional format 1-2-96)